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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/757,708	01/14/2004	Derek O' Hagan	PP-19768.002	3852

27476 7590 12/23/2008  
NOVARTIS VACCINES AND DIAGNOSTICS INC.  
INTELLECTUAL PROPERTY R338  
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EXAMINER
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POPA, ILEANA

ART UNIT	PAPER NUMBER
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1633

MAIL DATE	DELIVERY MODE
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12/23/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/757,708	O' HAGAN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	ILEANA POPA	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 06 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-28, 32-39, 42-48, 52, 54-64, 69, and 72-101 is/are pending in the application.
- 4a) Of the above claim(s) 4, 7, 11, 14, 19-22, 24, 25, 58-60, 62, 72-75, 84 and 85 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) See Continuation Sheet is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

Continuation of Disposition of Claims: Claims rejected are 1-3,5,6,8-10,12,13,15-18,23,26-28,32-39,42-48,52,54-57,61,63,64,69,76-83 and 86-101.

### **DETAILED ACTION**

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in the prior Office action.

2. Claims 29-31, 40, 41, 49-51, 53, 65-68, 70, and 71 have been cancelled.

Upon further consideration, claims 32, 33, 80-83, and 87-89 are hereby rejoined.

Claims 4, 7, 11, 14, 19-22, 24, 25, 58-60, 62, 72-75, 84, and 85 have been withdrawn. It is noted that claim 62 has been withdrawn because it is drawn to the non-elected species of RNA-virus-based plasmid (see the restriction requirement mailed on 03/10/2006); specifically, the DNA vector construct recited in the claim, wherein the vector construct is transcribed into an RNA vector which autonomously amplifies in a cell is the same as the non-elected species of RNA-virus-based plasmid (see the instant specification, paragraphs 0071-0074).

Claims 1-3, 5, 6, 8-10, 12, 13, 15-18, 23, 26-28, 32-39, 42-48, 52, 54-57, 61, 63, 64, 69, 76-83, and 86-101 are under examination.

### ***Response to Arguments***

#### ***Double Patenting***

3. Claims 1-3, 5, 6, 8-10, 12, 13, 15-18, 23, 26-28, 34-39, 42-48, 52, 54, 55, 61, 69, 76-79, and 90-101 remain and claims 32, 33, and 80-83 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 5-

Art Unit: 1633

19, 24-26, and 35-40 of U.S. Patent No. 6,884,435 for the reasons of record set forth in the non-final Office action of 02/06/2008. Applicant's arguments filed 08/06/2008 have been fully considered but they are not persuasive.

Applicant traversed the instant rejection on the grounds that the claims of US 6,884,435 do not teach microparticles “wherein the adsorbed first polynucleotide species constitutes at least 5 percent of the total weight of the microparticles, wherein the cationic surfactant is present during formation of the microparticles, and wherein no cationic surfactant removal step is conducted subsequent to formation of the microparticles”, as recited in the instant claim 1. With respect to the Examiner’s assertion that the patent specification discloses the polynucleotide as constituting 5% of the total weight of the microparticle and the microparticles as comprising 0.1 to 10% or 0.5 to 2% cationic surfactant, Applicant notes that he previously argued that the patent specification can be used as a dictionary to learn the meaning of a term in the patent claim; however, the disclosure of the patent may not be used as prior art for purpose of an obviousness-type double patenting rejection. Applicant also notes that the Examiner responded by alleging that the patent specification was used to define the microparticle characteristics in order to determine whether the claimed invention is an obvious variation of the invention claimed in the patent and further alleging that only those portions of the specification pertaining to the invention claimed in the patent were used (MPEP 804 II B, *In re Vogel*, 422 F.2d 438, 441-42, 16 USPQ 619, 622 (CCPA 1970) in which it was held that a certain portion of a the patent specification may be considered for purposes of an obviousness-type double patenting analysis).

Art Unit: 1633

With respect to this allegation, Applicant argues that, in this regard, the Vogel Court more fully explained its reasoning as follows:

The second analysis question is: Does any claim in the application define merely art obvious variation of an invention disclosed and claimed in the patent? In considering the question, the patent disclosure may not be used as prior art. *In re Boylan*, supra [392 F.2d 017, 55 CCPA 1041 (1968)]; *In re Aldrich*, 398 F.2d 855, 55 CCPA 1431 (1968). This does not mean that the disclosure may not be used at all. As pointed out above, in certain instances it may be used as a dictionary to learn the meaning of terms in a claim. It may also be used as required to answer the second analysis question above. We recognize that it is most difficult, if not meaningless, to try to say what is or is not an obvious variation of a claim. A claim is a group of words defining only the boundary of the patent monopoly. It may not describe any physical thing and indeed may encompass physical things not yet dreamed of. How can it be obvious or not obvious to modify a legal boundary? The disclosure, however, sets forth at least one tangible embodiment within the claim, and it is less difficult and more meaningful to judge whether that thing has been modified in an obvious manner. It must be noted that this use of the disclosure is not in contravention of the cases forbidding its use as prior art, nor is it applying the patent as a reference under 35 U.S.C. § 103, since only the disclosure of the invention claimed in the patent may be examined.

Thus, Applicant argues, the Court in Vogel, examined a "tangible embodiment" within the claim; however, the Court specifically refused to consider generic portions of the specification:

...We must now determine how much of the patent disclosure pertains to the invention claimed in the patent, which is a process to be performed with pork, to which all the patent claims are limited. The specification begins with certain broad assertions about meat sausages. These assertions do not support the patent claims. The patent claims recite "pork" and "pork" does not read on "meat." To consider these broad assertions would be using the patent as prior art, which it is not ....

Applicant argues that the present case is analogous because the patent claims recite an adsorbed "antigen comprising a polynucleotide" whereas column 14, lines 6-10 of the specification pointed out by the Examiner pertains to adsorbed macromolecules; just as "pork" does not read on "meat" (which is held in Vogel to include pork), an "antigen comprising a polynucleotide" does not read on a macromolecule and to consider the broad assertions regarding macromolecules would

Art Unit: 1633

be to use the patent as prior art. Similarly, Applicant argues, the patent claims recite a "cationic detergent" whereas column 14, lines 6-10 of the specification pointed out by the Examiner pertains to detergent; as above, to consider the broad assertions regarding detergents in the specification would be to use the patent as prior art. Thus, Applicant argues, claim 1 is patentable over the patent claims; all other claims depend, directly or indirectly, from claim 1 and are patentable over the patent claims for at least the same reasons. Therefore, Applicant requests the withdrawal of the rejection.

Applicant's arguments are acknowledged however, the rejection is maintained for the following reasons:

The argument that the instant case is analogous to *In re Vogel* is not found persuasive. As opposed to *In re Vogel* (where "The specification begins with certain broad assertions about meat sausages"), the disclosure in the '435 patent on which the Examiner relied in making the obviousness-type double patenting rejection is not a generic portion with which the specification begins and where the specification makes broad assertions about macromolecules and detergents. The teachings of the macromolecule constituting 5% of the total weight of the microparticle and of the microparticles as comprising 0.1 to 10% or 0.5 to 2% detergent specifically define the microparticles recited in the patent, which microparticles constitute a tangible embodiment. The patent specification defines that the macromolecule could be a polynucleotide and that the detergent could be a cationic detergent such as CTAB (column 5, lines 28-35 and 65-67) and therefore, the teachings of the macromolecule

Art Unit: 1633

constituting 5% (column 14, lines 6-10) and of the microparticles comprising 0.1 to 10% or 0.5 to 2% detergent (column 13, lines 30-37) do pertain to polynucleotides and cationic detergents such as CTAB. For these reasons, these portions of the specification can be relied on in making the instant rejection because they provide support for the microparticles recited in the patent claims and the rejection is maintained.

With respect to claims 32 and its dependent claims 33 and 80-83, the claims are obvious variants of the patent claims 1 and 16-18. It is noted that the patent specification defines that the cationic surfactant is exposed on the microparticle surface and that the exposed cationic surfactant binds the polynucleotide (column 11, line 65 through column 12, line 16). Therefore, the limitation of a first portion of the cationic surfactant being bound to the polymer and of a second portion of the cationic polymer forming a complex with the polynucleotide (the instant claim 32) is inherent to the microparticles recited in the patent claim 1.

4. Claims 1-3, 5, 6, 8-10, 12, 13, 15-18, 23, 26, 28, 34-37, 54, 55, 61, 69, 76-79, and 90-101 remain and claims 32, 33, and 80-83 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5, 11, 30, 31, 36, 37, 40, 43, 45-47, 58, 59, 70, and 71 of the U.S. Application No. 11/113,861 for the reasons of record set forth in the non-final Office action of 02/06/2008. Applicant's arguments filed 08/06/2008 have been fully considered but they are not persuasive.



Applicant traversed the instant rejection on the grounds that the double patenting issue has not yet matured for rational argument (i.e., the copending application has not issued as a patent and the claims may be amended/cancelled in the future). Applicant argues that, at a future time, the provisional double patenting rejection may be the only rejection remaining in the present application, in which case the rejection will be withdrawn in accordance with the provisions of MPEP 804. Furthermore, Applicant argues, Serial No. 11/113,861 is a continuation of Serial No. 09/581,772, which matured as '435 patent above; thus the arguments set forth above in connection with the '435 patent are to be considered for the present provisional double patenting rejection as well.

Applicant's arguments are acknowledged however, the rejection is maintained for the following reasons:

What is going to happen in the future is irrelevant. In the present time the double patenting rejection is not the only rejection remaining in the instant application and therefore, the rejection is maintained. Applicant also states that, since Application No. 11/113,861 is a continuation of Application No. 09/581,772 which matured as the U.S. Patent No. 6,884,435, the arguments set forth above are applicable to the provisional double patenting as well. In response to this statement, it is noted that the arguments set forth above were not found persuasive for the reasons stated above.

With respect to claims 32 and its dependent claims 33 and 80-83, the claims are obvious variants of the application claims 1, 5, 11, 30, and 31. It is noted that the application specification defines that the cationic surfactant is exposed on the

Art Unit: 1633

microparticle surface and that the exposed cationic surfactant binds the polynucleotide (p. 17, paragraphs 0069 and 0070). Therefore, the limitation of a first portion of the cationic surfactant being bound to the polymer and of a second portion of the cationic polymer forming a complex with the polynucleotide (the instant claim 32) is inherent to the microparticles recited in the patent claim 1.

***Claim Rejections - 35 USC § 102***

5. Claims 1-3, 5, 6, 8-10, 12, 13, 15-18, 23, 26-28, 34-39, 42-48, 52, 54-57, 61, 63, 64, 69, 76-79, 86, and 90-101 remain and claims 32, 33, 80-83, and 87-89 are rejected under 35 U.S.C. 102(e) as being anticipated by O'Hagan et al. (U.S. Patent No. 6,884,435, of record), as evidenced by Thalhamer et al. (Endocrine Regulations, 2001, 35: 143-166) for the reasons of record set forth in the non-final Office action of 02/06/2008. Applicant's arguments filed 08/06/2008 have been fully considered but they are not persuasive.

It is noted that most of the Applicant's arguments were previously presented in the reply filed on 02/06/2008; these arguments were answered in the non-final Office action mailed on 02/06/2008 and are not going to be repeated here.

Additionally, Applicant argues that: **(i)** the cited portions of O'Hagan refer to macromolecules and detergents and not to polynucleotides or cationic detergents; **(ii)** the values of 0.01:1 to 0.05:1 are not the same as the claimed 5% and 10% values; **(iii)** *Titanium Metals Corp.* pertains to situations in which an actual specific example in the prior art is found to lie within the claimed range; such a case is not pertinent to the

Art Unit: 1633

present invention because *Atofina* makes clear that the endpoint of a range is not a specific example, as alleged by the Examiner. Rather, Applicant argues, *Atofina* holds that “the disclosure of a range is no more a disclosure of the endpoints of the range than it is each of the intermediate points”; for these reasons, a disclosed range of 150-350°C in the prior art was held not to describe the claimed range of 330-450°C even if the 350°C endpoint value fell within the claimed range; and **(iv)** Example 7 in O'Hagan describes that the loading efficiency was seen to decrease with increasing target load; a loading efficiency of 5% is not demonstrated in Example 7. Applicant argues that the instant rejection is an anticipation rejection and thus pertains to what was actually done in O'Hagan, rather than what might or not might have been obvious in view of O'Hagan.

Applicant's arguments are acknowledged, however, they are not found persuasive for the following reasons:

The argument that the ranges taught by O'Hagan refer to macromolecules or detergents and not to polynucleotides or cationic detergents is not found persuasive because O'Hagan clearly defines that the macromolecule can be a polynucleotide and that the detergent can be a cationic detergent such as CTAB (column 5, lines 28-35 and 65-67) and therefore, the disclosed ranges do apply to polynucleotides and cationic detergents. MPEP states that A REFERENCE THAT CLEARLY NAMES THE CLAIMED SPECIES ANTICIPATES THE CLAIM NO MATTER HOW MANY OTHER SPECIES ARE NAMED”. The following is a citation from MPEP:

2123 [R-5] Rejection Over Prior Art's Broad Disclosure Instead of Preferred Embodiments

Art Unit: 1633

## I. PATENTS ARE RELEVANT AS PRIOR ART FOR ALL THEY CONTAIN

The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain." In re Heck, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983) (quoting In re Lemelson, 397 F.2d 1006, 1009, 158 USPQ 275, 277 (CCPA 1968)).

A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. Merck & Co. v. Biocraft Laboratories, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989). See also > Upsher-Smith Labs. v. PamLab, LLC, 412 F.3d 1319, 1323, 75 USPQ2d 1213, 1215 (Fed. Cir. 2005) (reference disclosing optional inclusion of a particular component teaches compositions that both do and do not contain that component); < Celeritas Technologies Ltd. v. Rockwell International Corp., 150 F.3d 1354, 1361, 47 USPQ2d 1516, 1522-23 (Fed. Cir. 1998) (The court held that the prior art anticipated the claims even though it taught away from the claimed invention. "The fact that a modem with a single carrier data signal is shown to be less than optimal does not vitiate the fact that it is disclosed.").

For the same reasons as above, the argument regarding Example 7 is not found persuasive. The fact of the matter is that O'Hagan discloses the claimed values. While Applicant is right in pointing out that the values of 0.01:1 to 0.05:1 are not the same as the claimed 5% and 10% values, O'Hagan also teaches a polynucleotide to microparticle ratio of 0.25:1 (see column 14, lines 1-10), i.e., the polynucleotide constitutes 20% of the total weight of the microparticles. Since MPEP states that patents are relevant art for all they contain, by teaching that the polynucleotide constitutes 20% of the total weight of the microparticles, O'Hagan anticipates the values of at least 5% (claim 1), 10 to 30% (claim 27), and 10 to 20% (claims 28, 91, and 93).

Applicant argues that *Atofina* makes clear that the endpoint of a range is not a specific example. This argument is not found persuasive because in *Atofina* the claimed range was 330-450°C without specifically reciting the value of 350°C which is the endpoint value of the range of 150-350°C disclosed by the art. In the instant case,

Art Unit: 1633

the claims specifically recite the endpoint of 20% and O'Hagan specifically discloses a range having the endpoint value of 20%; therefore, O'Hagan anticipates the claimed 20% (or at least 5%) value.

With respect to claims 32 and its dependent claims 33 and 80-83, the claims are anticipated by O'Hagan. It is noted that O'Hagan et al. teach that the cationic surfactant is exposed on the microparticle surface and that the exposed cationic surfactant binds the polynucleotide (column 11, line 65 through column 12, line 16). Therefore, the limitation of a first portion of the cationic surfactant being bound to the polymer and of a second portion of the cationic polymer forming a complex with the polynucleotide (the instant claim 32) is inherent to the microparticles recited in the patent claim 1.

With respect to the limitation recited in claims 87-89, O'Hagan et al. teach that the microparticle composition can comprise additional microparticles with the adjuvant entrapped or adsorbed on their surface (column 14, lines 35-51).

6. No claim is allowed. No claim is free of prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILEANA POPA whose telephone number is (571)272-5546. The examiner can normally be reached on 9:00 am-5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Voitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1633

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ileana Popa/  
Examiner, Art Unit 1633

Application/Control Number: 10/757,708  
Art Unit: 1633

Page 13